REMARKS

Claims 13-18 and 24-33 are pending. Claims 13, 18 and 28 are independent.

Rejections of Claims 13-18 and 24-30

Claims 13, 14, 16-18, 25 and 27 were rejected under 35 U.S.C. § 102(b), with the Office Action relying on U.S. Patent No. 4,552,555 to Theeuwes ("Theeuwes").

Claims 13, 14, 16-18, 24, 25 and 27-30 were rejected under 35 U.S.C. § 103(a), with the Office Action relying on U.S. Patent No. 5,833,652 to Preissman ("Preissman") in view of Theeuwes.

Claims 15 and 26 were rejected under 35 U.S.C. § 103(a), with the Office Action relying on Preissman and Theeuwes in view of U.S. Patent No. 4,953,561 to Guirguis.

The Applicant respectfully requests reconsideration of those rejections in view of the following remarks.

Applicant's Invention and Example Embodiments

Applicant's invention is directed to a device for modifying a fluid moving through a vessel prior to the ejection of the fluid from the vessel into the body of a patient. An example of an embodiment within the scope of at least the independent claims is illustrated in Applicant's Figure 1, reproduced on the following page:

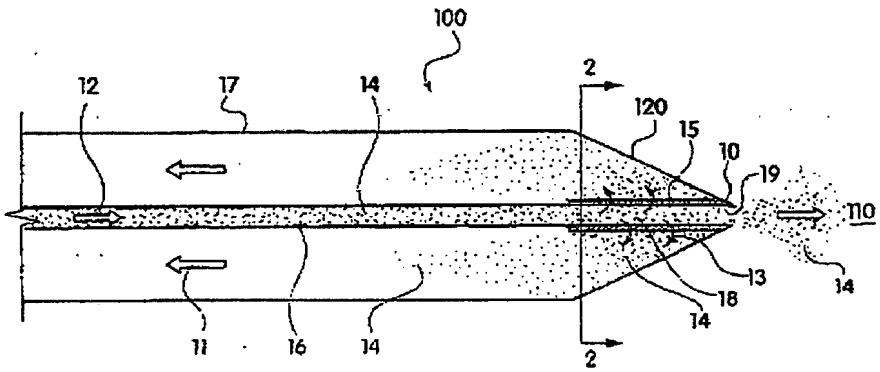

FIG. 1

In this embodiment, the vessel is a catheter 100 comprising a first lumen 16, a second lumen 17, and an exit orifice 19 located at a distal end of the first lumen. A mixing or modification chamber 18 is positioned within the first lumen 16 proximal to the exit orifice 19. The arrows 13 show the flow of compounds through a selectively permeable membrane 15 in a passageway located proximal to the exit orifice 19, the passageway being positioned between the chamber 18 and the second lumen 17. The passageway fluidly connects the chamber 18 to the second lumen 17, and the selectively permeable membrane 15 is positioned to selectively pass compounds through the passageway between the chamber 18 and the second lumen 17.

As an example of a use of this embodiment, fluid including a therapeutic agent and a solvent may be transported through the first lumen 16 from a proximal end of the catheter 100 to a distal end of the catheter 100. Before reaching the exit orifice 19, the fluid passes into the fluid mixing or modification chamber 18 located within the first lumen 16. Because the solvent of the fluid is able to pass through the selectively permeable membrane 15, solvent is drawn away from the fluid in the chamber 18 and into the second lumen 17. Thus, the amount of solvent in the fluid is lowered prior to delivery of the fluid through the exit orifice 19 to the patient. While this

example involves extraction of a compound from the fluid while the fluid is in the fluid modification chamber, the device may also be used for addition of a compound to the fluid while the fluid is in the fluid modification chamber.

The Theeuwes Patent

The Theeuwes device is a chamber that can be used in an intravenous (IV) delivery system for adding a therapeutic agent to a fluid. An example of the Theeuwes system is illustrated in Figure 1. Fluid 12 from container 11 travels through connector 16, drip chamber 18 and tubing 20 into agent formulation chamber 22. In the agent formulation chamber 22, the fluid mixes with a pharmaceutical agent. Thereafter, the mixed fluid exits the agent formulation chamber 22 and passes through tubing 20 to an adapter-needle assembly for entering a patient, as in a conventional IV.

The Office Action identifies reference numerals from Theeuwes corresponding to Figure 6. The Office Action states that Applicant's claimed "first lumen" is met by the tubing portion 45 proximal to chamber 60, that the claimed "exit orifice" is at numeral 62b, that the claimed "second lumen" is met by the tubing portion 45 distal to chamber 60, that the claimed "mixing chamber" is the chamber 60, and that the "passageway" is membrane 64.

While the Applicant respectfully disagrees with this alleged correspondence between these claim elements and Theeuwes, claims 13 and 18 above recite, inter alia, that the second lumen is connected to the mixing chamber "at a location proximal to the exit orifice." Thus, even if one were to accept, for the sake of argument, that the claimed "exit orifice" is at numeral 62b, that the claimed "second lumen" is met by the tubing portion 45 distal to chamber 60, and that the claimed "mixing chamber" is the chamber 60, the claims would still not be met by

Theeuwes at least because the so-called "second lumen" (tubing portion 45 distal to chamber 60) is not connected to the so-called "mixing chamber" (chamber 60) at a location proximal to the so-called "exit orifice" (at 62b).

Accordingly, the Applicant respectfully submits that claims 13 and 18, and all claims depending from claims 13 and 18, are not anticipated by Theeuwes. The remaining claims were not rejected on anticipation grounds.

The Obviousness Rejection Based on Preissman and Theeuwes

The Office Action states, "[I]t would have been obvious to one of ordinary skill in the art at the time the invention was made to add the selectively permeable membrane of Theeuwes into the passageways (14) of Priessman because the membrane and the dual lumens would perform the same operations in combination and one of ordinary skill in the art would have expected that adding the membrane would produce the predictable result of adding or extracting a component from a medical fluid." (Office Action, page 3). With respect to this rejection, the Applicant respectfully submits the following comments.

The Priessman reference has been cited against the claims in prior rejections in prior Office Actions (see Office Actions dated 11/30/05 and 6/28/06). Those rejections, appropriately, were later withdrawn (see Office Action dated 5/10/07).

The Priessman reference is directed to a mixing catheter that has a first lumen 10 and a second lumen 12 that are connected together at connecting passages 14. According to Priessman, "This arrangement permits the two components passing through the first and second lumens 10 and 12 to mix within first lumen 10 prior to exiting an exterior opening 16 formed at distal end 8." (col. 2, lines 45-48).

The Priessman reference is explicitly directed to mixing two components from the two lumens. Its stated purpose is to combine the materials from the two lumens, as opposed to extracting, filtering or separating them.

While permeable membranes have been well known for many years, there is no reason in the prior art for adding such a membrane to the Priessman device. In order for a modification to have been obvious, there must be some reason in the prior art for making the combination. *KSR Int'l Co. v. Teleflex Inc.* (2007). The lack of a basis in the prior art for adding a membrane to the device of Priessman was the reason why the previous rejections based on Priessman were withdrawn. (See Response dated 8/16/06).

The Theeuwes reference discloses a membrane as known in the art, but the Theeuwes reference, like the other prior art, lacks any reason for why one would add a membrane to the Priessman device. In Theeuwes, the membrane is for the express purpose of controlling the rate of drip through the IV tube to the patient. Theeuwes states:

> [F]ilm 64 [is] formed of a material for controlling the flow of fluid and agent from chamber 60. ... The polymeric film according to the mode of the invention is used in a presently preferred embodiment for governing the rate of release of solution containing agent from chamber 60, that is, agent release and fluid flow through chamber 60.

(Col. 6, lines 56-66 (emphasis added)).

In Theeuwes, the membrane is for controlling the rate of fluid drip. There is simply no reason to add the rate release membrane of Theeuwes to the Priessman device. In Theeuwes, it is the rate of drip from the chamber 60 that governs the amount of fluid received through the IV by the patient. In Priessman, however, the connecting passages 14 do not at all constrain the amount of fluid passing through first lumen 10 and thus cannot control the fluid delivery rate to the patient as in Theeuwes.

More importantly, nothing in either Priessman or Theeuwes suggests, as the Office Action states, adding the membrane of Theeuwes to Priessman to "produce the predictable result of adding or extracting a component from a medical fluid." Contrary to this statement, the Theeuwes membrane is not described as "adding or extracting a component from a medical fluid" but rather is for controlling drip rate, as described above.

Not only is nothing added to the fluid by the membrane of Theeuwes, but there is simply no reason for applying the membrane of Theeuwes to the Priessman device for the purpose of subtracting something from the fluid. For example, Applicant's new dependent claims 32-34 recite that "the selectively permeable membrane is adapted to extract a compound from fluid in the mixing chamber [or fluid modification chamber]." In the independent claims 13, 18 and 28, the membrane is defined as being located between the mixing chamber [or fluid modification chamber] and the second lumen, so that a compound can be extracted from the mixing chamber through the membrane into the second lumen. In Priessman, there is simply no reason why one would add a membrane for the purpose of extracting a compound from the first lumen 10 into the second lumen 12 through the connecting passages 14. Extracting a compound from the first lumen would result in that compound not being delivered to the patient, and such a result is directly contrary to the stated objective of Priessman, which is to have the components from the first and second lumens "mixed" and then to have the combined mixture "applied to the target site" of a patient. (col. 1, lines 42-45).

Accordingly, just like there is no suggestion in Theeuwes for using a membrane for "adding" a component as the Office Action states, there is no suggestion for using a membrane for "subtracting" a component from the first lumen of Priessman, and such a modification would be contrary to the Priessman reference itself.

CONCLUSION

For the foregoing reasons, the Applicant respectfully requests reconsideration of this application. While no fees are believed to be due, the Office is authorized to charge any underpayment or credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,

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Douglas E. Ringel
Reg. No. 34,416

KENYON & KENYON LLP
1500 K Street, N.W.
Washington, D.C. 20005
202-220-4200 (phone)
202-220-4201 (facsimile)

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